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ATTORNEY DOCKET NO.: 0492611-0513 (MIT 8853)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Cohen et al. Examiner:
Serial No.: 10/667,956 Art Unit:
Filing Date: September 22, 2003
Title: METHODS AND APPARATUS FOR DETERMINING CARDIAC
OUTPUT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:


TRANSMITTAL LETTER

Enclosed are the following documents:

1. Form PTO-1449 (3 pages);
2. Information Disclosure Statement (6 pages);
3. Cited Art (53 references); and
4. Return Postcard

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

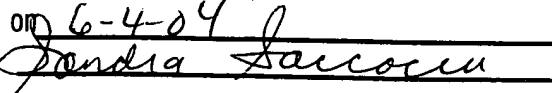

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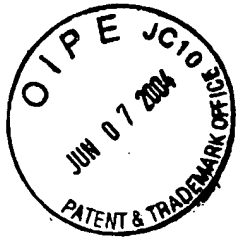
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Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
☐ A *supplemental* Information Disclosure Statement.

Certificate of Mailing

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6-4-04 Sandra Saccocia
Date Signature

Sandra Saccocia

Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☒ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
 - ☐ Certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ A copy of each cited reference not indicated with an asterisk is included;

☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

☒ Does not contain non-English language citations;

☐ Does contain non-English language citations, of which the following is a concise

explanation:

- [] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: 6-4-04

Monica R. Gerber
Monica R. Gerber, M.D., Ph.D.
Reg. No.: 46,724

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ATTY. DOCKET:
0492611-0513
(MIT 8853)

IN RE
APPLICATION NO.:
10/667,956

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANT: Cohen, et al.,

FILING DATE:
September 22, 2003

GROUP:

U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	6,485,431	Campbell	November 26, 2002	600	526
	6,368,284	Bardy	April 9, 2002	600	508
	5,535,753	Petrucelli et al.	July 16, 1996	128	672
	5,423,322	Clark et al.	June 13, 1995	128	672
	5,400,793	Wesseling	March 28, 1995	128	672
	5,183,051	Kraidin et al.	February 2, 1993	128	687
	5,101,828	Welkowitz et al.	April 7, 1992	128	668
	4,429,701	Goor et al.	February 7, 1984	128	713

U.S. PATENT APPLICATIONS

Examiner's Initials:	Publication Number:	Applicant:	Publication Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Aboy, et al., "Automatic Detection Algorithm for Physiologic Pressure Signal Components", <i>Proc. 2nd Joint EMBS/BMES Conference 2002</i> : 196-197.
	Antonelli, et al., "Wavelet Transform Analysis of the Arterial Pressure Signal", <i>Computers in Cardiology</i> , 1994: 568-571.
	Antonutto, et al., "Assessment of Cardiac Output from Noninvasive Determination of Arterial Pressure Profile in Subjects at Rest", <i>Eur. J. Appl. Physiol.</i> 69 : 183-188, 1994.
	Appel, et al., "Beat-to-Beat Variability in Cardiovascular Variables: Noise or Musice?", <i>J. Am. Coll. Cardiol.</i> , 14 : 1139-1148, 1989.
	Bourgeois, et al., "Characteristics of Aortic Diastolic Pressure Decay with Application to Continuous Monitoring of Changes in Peripheral Resistance", <i>Circ. Res.</i> , 35 : 56-66, 1974.
	Bourgeois, et al., "Continuous Determination of Beat-to-Beat Stroke Volume from Aortic Pressure Pulses in the Dog", <i>Circ. Res.</i> , 39 (1): 15-24, 1976.

FORM PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		ATTY. DOCKET: 0492611-0513 (MIT 8853)	IN RE APPLICATION NO.: 10/667,956
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT: Cohen, et al.,	
				FILING DATE: September 22, 2003	GROUP:
	Brubakk, A., "Use of Simulation Model for Estimating Cardiac Output from Aortic Pressure Curves", <i>Med & Biol. Eng. & Comput.</i> , 16 : 697-706, 1978.				
	Cerutti, et al., "Beat-to Beat Stroke Volume Estimation from Aortic Pressure Signal in Conscious Rats: Comparison of Models", <i>Am. J. Physiol.</i> , 281 : H1148-H1155, 2001.				
	Cibulski, et al., "Pressure Methods for Estimating Right and Left Ventricular Stroke Volumes", <i>Am. J. Physiol.</i> , 225 (6): 1460-1466, 1973.				
	Connors, et al., "The Effectiveness of Right Heart Catheterization in the Initial Care of Critically Ill Patients", <i>JAMA</i> , 276 (11):889-897, 1996.				
	Cundick, et al., "Clinical Comparison of Pressure-Pulse and Indicator-Dilution Cardiac Output Determination", <i>Circulation</i> , 62 (2): 371-376, 1980.				
	Ehlers, et al., "Cardiac Output Measurements. A Review of Current Techniques and Research", <i>Ann. Biomed. Eng.</i> , 14 (3): 219-239, 1986.				
	Fry, et al., "Measurement of Pulsatile Blood Flow by the Computed Pressure-Gradient Technique", <i>IRE Trans. Med. Electron., ME.</i> 6 : 259-264, 1959.				
	Fry, et al., "A Catheter Tip Method for Measurement of the Instantaneous Aortic Blood Velocity", <i>City Res.</i> , 4 : 627-632, 1956.				
	Gratz, et al., "Continuous Noninvasive Cardiac Output as Estimated from the Pulse Contour Curve", <i>J. Clin. Monit.</i> , 8 :20-27, 1992.				
	Greenfield, et al., "Relationship Between Instantaneous Aortic Flow and the Pressure Gradient", <i>Cir Res.</i> , 17 : 340-348, 1965.				
	Haffty, et al., "Noninvasive Tracking of Peripheral Resistance by Ear Densitography", <i>Chest</i> , 83 (5); 771-775, 1983.				
	Hamilton, et al., "The Measurement of the Stroke Volume from the Pressure Pulse", <i>Am. J. Physiol.</i> , 148 (14): 14-24, 1947.				
	Harley, et al., "Pressure-Flow Studies in Man: Evaluation of the Duration of the Phases of Systole", <i>J. Clin. Invest.</i> , 48 : 895-905, 1969.				
	Herd, et al., "Arterial Pressure Pulse Contours During Hemorrhage in Anesthetized Dogs", <i>J. Appl. Physiol.</i> , 21 (6): 1864-1868, 1966.				
	Houtman, et al., "Non-Invasive Cardiac Output Assessment During Moderate Exercise: Pulse Contour Compared with co2 Rebreathing", <i>Clin. Physiol.</i> , 19 : 230-237, 1999.				
	Imholz, et al., "Fifteen Years Experience with Finger Arterial Pressure Monitoring: Assessment of the Technology", <i>Cardiovasc. Res.</i> , 38 : 605-616, 1998.				
	Jones, et al., "Velocity of Blood Flow and Stroke Volume Obtained from the Pressure Pulse", <i>J. Clin. Invest.</i> , 38 : 2087-2090, 1959.				
	Kenner, T., "Arterial Blood Pressure and its Measurement" <i>Basic Res. Cardiol.</i> , 83 (2): 107-121, 1988.				
	Kouchoukos, et al., "Estimation of Stroke Volume in the Dog by Pulse-Contour Method", <i>Cir. Res.</i> , 26 : 611-623, 1970.				
	Levett, et al., "Thermodilution Cardiac Output: A Critical Analysis and Review of the Literature", <i>J. Surg. Res.</i> , 27 : 392-404, 1979.				
	Linton, et al., "Estimation of Changes in Cardiac Output from the Arterial Blood Pressure Signal in the Upper Limb", <i>Br. J. Anaesth.</i> , 86 : 486-496, 2001.				
	Martin, et al., "Application of Pattern Recognition and Image Classification Techniques to				

FORM PTO-1449 (REV. 8-83)	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET: 0492611-0513 (MIT 8853)	IN RE APPLICATION NO.: 10/667,956
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>		APPLICANT: Cohen, et al.,	
		FILING DATE: September 22, 2003	GROUP:

	Determine Continuous Cardiac Output from the Arterial Pressure Signal", <i>IEEE Trans. Biomed. Eng.</i> , 41 (10): 913-920, 1994.
	McDonald, D.A., "Left Ventricular Output Derived from the Time-Derivative and Phase Velocities of the Aortic Pressure Wave", <i>Med. Biol. Eng.</i> , 11 (6): 678-690, 1973.
	Navakatiyan, et al., "A Real-Time Algorithm for the Quantification of Blood Pressure Signals", <i>IEEE Trans. Biomed. Eng.</i> , 49 (7): 662-670, 2002.
	Nichols, et al., "Continuous Cardiac Output Derived from the Aortic Pressure Signal: A Review of Current Methods", <i>Biomed. Eng.</i> , 8 (9): 376-379, 1973.
	Osborn, et al., "The Measurement of Relative Stroke Volume from Aortic Pulse Contour Pulse Pressure", <i>Vasc. Dis.</i> , 5 (3): 165-177, 1968.
	Perrott, et al., "An Efficient Approach to Arma Modeling of Biological Systems with Multiple Inputs and Delays", <i>IEEE Trans. Biomed. Eng.</i> , 43 (1): 1-14, 1996.
	Redling, et al., "Noninvasive Cardiac Output Estimation: A Preliminary Study", <i>Biol. Cybern.</i> , 77 : 111-122, 1997.
	Remington, et al., "The Construction of A Theoretical Cardiac Ejection Curve from the Contour of the Aortic Pressure Pulse", <i>Am. J. Physiol.</i> , 144 : 546-556, 1945.
	Robin, E.D., "Death by Pulmonary Artery Flow-Directed Catheter (Editorial). Time for a Moratorium?", <i>Chest</i> , 92 (4): 727-731, 1987.
	Starmer, et al., "Evaluation of Several Methods for Computing Stroke Volume from Central Aortic Pressure", <i>Circ. Res.</i> , 33 : 139-148, 1973.
	Starr, et al., "Studies Made by Simulating Systole at Necropsy. Iv. on the Relation Between Pulse Pressure and Cardiac Stroke Volume, Leading to a Clinical Method of Estimating Cardiac Output from Blood Pressure and Age", <i>Circulation</i> , 9 : 648-663, 1954.
	Tajimi, et al., "Evaluation of Pulse Contour Methods in Calculating Stroke Volume from Pulmonary Artery Pressure Curve (Comparison with Aortic Pressure Curve). <i>Eur. Heart J.</i> , 4 : 502-511, 1983.
	Verdouw, et al., "Stroke Volume from Central Aortic Pressure? A Critical Assessment of the Various Formulae as to Their Clinical Value", <i>Basic Res. Cardiol.</i> , 70 : 377-389, 1975.
	Warner, et al., "The Role of Computers in Medical Research", <i>JAMA</i> , 196 : 944-949, 1966.
	Warner, et al., "Quantitation of Beat-to-Beat Changes in Stroke Volume from the Aortic Pulse Contour in Man", <i>J. Appl. Physiol.</i> , 5 : 495-507, 1953.
	Welkowitz, et al., "Noninvasive Estimation of Cardiac Output", <i>IEEE Trans. Biomed. Eng.</i> , 38 (11): 1100-1105, 1991.
	Wellstead, et al., "Least-Squares Identification of Closed-Loop Systems", <i>Int. J. Control</i> , 21 (4): 689-699, 1975.
	Womersley, J.R., "Method for the Calculation of Velocity, Rate of Flow and Viscous Drag in Arteries When the Pressure Gradient is Known", <i>J. Physiol.</i> , 127 : 553-563, 1955.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.